GEORGIA INSTITUTE OF TECHNOLOGY

BIOSAFETY MANUAL

POLICIES AND PROCEDURES

MAY 2004

Georgia Institute of Technology
Research and Graduate Studies

May 27, 2004

MEMORANDUM

TO: Georgia Institute of Technology Faculty, Staff, and Students

FROM: Charles Liotta
Vice Provost for Research
and Dean of Graduate Studies

Charles L Liotta

SUBJECT: Policies and Procedures Governing Research and Teaching that Involve Biohazards and Recombinant DNA

The Georgia Institute of Technology is among the nation's top research universities, distinguished by its commitment to improving the human condition through advanced science and technology and by its dedication to academics and research.

We are committed to the highest standards of integrity in all areas of research conducted at the Institute. That commitment includes our resolve that all research conducted at Georgia Tech will be done in accordance with strict ethical standards and in compliance with Federal, State, and Institute regulations and policies. This commitment additionally ensures the protection of personnel from exposure to infectious or hazardous agents; prevents environmental contamination, and creates a safe environment for high quality research.

These standards are reflected in these policies and procedures statements. I am pleased to sponsor these documents which guide research and teaching involving biohazards and recombinant DNA. My congratulations to the Office of Environmental Health and Safety and to the Institutional Biosafety and Biohazards Board on their contributions to these vitally important policies and procedures.

c: Wayne Clough
Jean-Lou Chameau

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The Institutional Biosafety and Biohazards Board (IBBB) has the important mission of reviewing all applications for research, teaching, and training that involve the use of recombinant DNA, select agents, pathogenic organisms other than select agents, etiological agents, and certain human samples at Georgia Tech and ensuring that the proposed activities comply with the federal regulations governing them. IBBB is responsible for maintaining Georgia Tech's registration with the National Institutes of Health's Office of Biotechnology Activities (OBA). IBBB works closely with Georgia Tech's Responsible Official and Biosafety Officer in the Office of Environmental Health

and Safety.

The Institutional Biosafety and Biohazards Board holds meetings as needed to review applications proposing use of recombinant DNA, select biological agents, pathogenic organisms other than select agents, etiological agents, and certain human samples.

To apply for IBBB review, send a completed, signed application to: Office of Research Compliance, mail code 0420. Refer to www.research.gatech.edu/biosafety.htm for more information on the Institutional Biosafety and Biohazards Board.

ENVIRONMENTAL HEALTH & SAFETY

Environmental Health & Safety are responsible for biosafety on Georgia Institute of Technology's campus. The Environmental Health and Safety department also provides guidance and oversight to mandated programs, responds to concerns about indoor environments, conducts safety inspections of laboratories and support areas, provides fire safety services, processes and manages hazardous materials for proper disposal, provides emergency response for hazardous materials incidents / accidents (spills), and provides safety training.

Director	Ed Guida	404/894-6118
Biosafety Officer	Lee Zacarias	404/894-6119
Chemical Safety Coordinator	Debbie Wolfe-Lopez	404/385-2964
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PURPOSE

This document provides a comprehensive source for all matters covering the use of Biosafety Level 1 (BSL-1), Biosafety Level 2 (BSL-2), and Biosafety Level 3 (BSL-3) contaminants handled in the laboratories located at Georgia Institute of Technology or laboratories located off-campus under the supervision of Principal Investigators associated with Georgia Institute of Technology. Specifically, it describes the procedures to be used to insure a safe working environment while working with regulated recombinant DNA systems, infectious microorganisms, select biological agents, or human cell cultures and human body fluids. This manual will be reviewed annually by the Biosafety Officer for changes or corrections to ensure that it is timely and accurate.

SECTION I- RESPONSIBILITIES

A. Georgia Institute of Technology

The Institute and its administrative officers are ultimately responsible for the following:

3. Developing and maintaining appropriate policies regarding the conduct of potentially biohazardous research, education, and service activities.
4. Developing mechanisms for insuring faculty and staff adherence to biosafety policies.
5. Providing the resources necessary for the construction of safe research and teaching facilities and for the implementation of the biosafety program.
6. Providing adequate resources for the dissemination of information on biohazards and biosafety procedures, including training programs and workshops.
7. Providing resources for appropriate medical surveillance measures to protect the health and safety of employees.
8. Providing appropriate and sufficient legal protection for faculty and staff members who conduct activities in compliance with appropriate regulations and guidelines.

B. Biosafety Officer

The Institute's Biosafety Officer has responsibility for the daily administration of standards set by the IBBB and acts as the agent of the committee in charge of their implementation. Other responsibilities include:

1. Review protocols and Memorandum of Understanding (if appropriate) and assignment to the IBBB for review.
2. Arranging for initial and periodic inspections of laboratories used in biohazardous research to insure that standards set by the IBBB are followed.
3. Providing technical advice to Principal Investigators and to the Institutional Biohazards and Biosafety Board on research safety procedures.
4. Organizing and conducting informational and training seminars and workshops on biohazards for the Institute community.
5. Arranging with Georgia Tech Health Services for appropriate medical surveillance of student personnel working with certain biohazardous agents or as required by the Institutional Biosafety and Biohazards Board.
6. Providing technical advice to the Institute regarding biohazard safety needs and requirements for projects involving the renovation or construction of laboratory or other facilities in which biohazards will be used.

C. Responsible Official

The Responsible Official has the following responsibilities:

1. Submit an application regarding select agents to Center for Disease Control (CDC) or Department of Health and Human Services (DHHS) for Georgia Tech
2. Establish security for the select agent or toxin laboratories
3. Develop a safety plan for the select agents laboratories
4. Regularly inspect laboratories containing select agents
5. Develop an emergency response plan for laboratories housing select agents
6. Perform training to all individuals that work with the select agent/toxin
7. Keep thorough records of individuals, inventories, and areas where agents/toxins are used
8. Notify DHHS to report thefts, losses, or releases of select agent/toxin
9. Notify DHHS before destroying a select agent/toxin

D. Institutional Biosafety and Biohazards Board

The Institute's Institutional Biosafety and Biohazards Board (IBBB) serves to advise the Institute's administration on policies pertaining to Biohazardous Research, teaching, and service activities. The committee recommends standards under which biohazardous activities should be conducted and reviews projects for compliance with appropriate federal, state, and Institutional guidelines and regulations. Other specific responsibilities include:

1. Review for appropriateness and adequacy the containment levels and safety measures proposed and/or used in research and teaching.
2. Assess the adequacy of containment facilities for biohazards of select agents, pathogens, ethological agents, certain human samples, and rDNA molecules as required by NIH or other funding or regulatory agencies.
3. Develop with the Biosafety Officer informational and training seminars and workshops on biohazards for the Institute community.
4. Periodically review biohazardous research being conducted at the Institute to insure that the requirements of the Institute, funding sources, and regulatory agencies are being fulfilled.
5. Recommend to the Institute Administration appropriate sanctions for non-compliance with biosafety standards, guidelines, or regulations.
6. Develop with the Biosafety Officer emergency plans covering accidental spills and personnel contamination resulting from biohazardous research.

The minimum composition of the Institutional Biosafety and Biohazard Boards (IBBB) is specified in the NIH "Guidelines for Research Involving Recombinant DNA Molecules". The IBBB shall have at least 5 members selected to have expertise and experience in recombinant DNA technology and capable of assessing the safety of rDNA research

experiments and any potential risks to public health and the environment. The IBBB shall include at least 2 members who are not affiliated with the Institute by other than their committee membership. In addition, when experiments using mammals or plants require prior IBBB approval, there shall be at least one (1) scientist with expertise in plant pathogens or plant pest containment and one (1) scientist with mammalian containment expertise on the IBBB.

E. Department/Unit Heads

Department/Unit Heads have the following responsibilities:

1. To insure that, prior to initiation of work, each investigator or laboratory director using a biohazardous agent files a Risk Assessment and protocols with the appropriate grant application and a Memorandum of Understanding and Agreement with the Institutional Biosafety and Biohazards Board through the Biosafety Officer.
2. To ensure that staff and students have had instruction in safety procedures in teaching laboratories or field situations where biohazardous agents are used.
3. To determine that appropriate facilities and safety equipment are available for proposed research or instruction involving biohazardous agents.
4. To provide leadership in laboratory safety at the management level in the department.

F. Faculty and Professional Staff (Principal Investigators)

Developing and maintaining a healthful and safe work environment depends on the day-to-day supervision of investigative practices by personnel with a positive safety attitude. The principal investigator (PI), laboratory director, project supervisor, or teaching supervisor is responsible for knowing and complying fully with Georgia Institute of Technology, the State of Georgia, and Federal rules, regulations, and/or standards. The principal investigator and/or laboratory supervisor shall:

1. Determine the known or potential biohazards associated with the proposed experiments. For recombinant DNA experiments, the principal investigator shall not initiate or modify those experiments requiring approval of the Institutional Biohazards and Biosafety Board (Institutional Biosafety and Biohazards Board) until that proposed research or modification has <u>received approval from the Institutional Biosafety and Biohazards Board (IBBB)</u> and has met all requirements including those of the appropriate governing State and/or Federal agencies.
2. Provide those personnel under his/her supervision with knowledge of biohazards to which they may be exposed and safety procedures to be followed. This is to be accomplished by:
    a. The PI being knowledgeable of good laboratory safety practice and a positive safety attitude.
    b. Posting or making readily available to the laboratory staff copies of the protocols that describe potential biohazards and the precautions

to be taken. These protocols as well as biosafety concerns should be produced in the form of a standard operating procedure (SOP) for the work.

c. Providing laboratory staff with formal and informal instruction and training in the practices and techniques required to ensure safety and in the procedures for dealing with accidental spills, personnel contamination, and other laboratory accidents. For training logs relative to select or infectious agents, see Appendix D.
d. Informing the laboratory staff of the reasons and provisions for any precautionary medical practices (e.g. physical examinations, serum collection, and vaccinations).
e. Supervising the performance of the staff to ensure that required safety practices and techniques are employed.

3. Immediately report in writing to the Biosafety Officer any accident, exposure of personnel, suspected illness, escape from containment of biohazardous agents, and significant problems pertaining to the operation and implementation of containment practices and procedures.
4. Provide physical examinations and other medical surveillance of personnel when required by the nature of the experiments.
5. Insure the integrity of the physical containment (e.g. biological safety cabinets) and biological containment (e.g. purity and genotypic and phenotypic characteristics).
6. Maintain knowledge of and adhere to the permit requirements of federal and state agencies for interstate and international movement of biohazardous agents.
7. The principal investigator is responsible for keeping the laboratory secure from unauthorized persons.

SECTION II- BIOHAZARDOUS RESEARCH

1. Institutional Biosafety and Biohazards Board (IBBB) – The Institute's Committee is appointed by the Vice Provost of Research. IBBB has the important mission of reviewing all applications for research, teaching, and training that involve the use of recombinant DNA, select agents, pathogenic organisms other than select agents, etiological agents, and certain human samples at Georgia Tech and ensuring that the proposed activities comply with the federal regulations governing them. IBBB is responsible for maintaining Georgia Tech's registration with the National Institutes of Health's Office of Biotechnology Activities (OBA).
2. Biohazard – infectious agents, or parts thereof, presenting a real or potential risk to the well-being of man, other mammals, or plants hazardous to environmental safety directly through infection or indirectly through disruption of the environment; and venomous vertebrate or invertebrate animals, or toxins thereof, presenting a real or potential risk to man.
3. Class 2 Agents – are those agents which may produce disease of varying degrees of severity from exposure by injection, ingestion, adsorption, and inhalation, but which are contained by good laboratory techniques are included in this level. Class 2 Agents must be handled using Biosafety Level 2 or greater containment facilities and practices.
4. Class 3 Agents – are indigenous or exotic agents or exotic strains of indigenous agents which may cause serious or potentially lethal disease as a result of exposure by inhalation. Class 3 agents are those that must be handled using Biosafety Level 3 or greater containment facilities and practices.
5. Genetic Engineering – the genetic modification of organisms by recombinant DNA techniques.
6. Regulated Article – any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 7 CFR 40.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown or any product altered or produced through genetic engineering which the Deputy Administrator (USDA) determines is a plant pest or has reason to believe is a plant pest.
7. Restricted Mammalian Pathogens – nonindigenous pathogens of domestic livestock and poultry that may require special containment strategies and facilities not generally discussed in this manual.
8. Recombinant DNA- either (1) molecules that are constructed outside living cells by joining in natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) molecules that result from the replication of those described in (1) above. In addition, synthetic DNA segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart.

9. Infectious Biological Agents- include biological agents and biologically derived materials that present a risk or potential risk to the health of humans or mammals, either directly through infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include the following:
   i. Human, mammals, and plant pathogens (bacteria, parasites, fungi, viruses);
   ii. All human blood, blood products, tissues, and certain body fluids (excluding routine use of human blood and body fluid for clinical purposes);
   iii. Cultured human or mammalian cells and potentially infectious agents these cells may contain;
   iv. Clinical specimens; and
   v. Infected mammals and mammalian tissues.

SECTION III- BIOHAZARDOUS WASTE

It is expected that investigators using biohazardous agents and/or producing biomedical wastes as defined below will comply with the rules promulgated by the Georgia Environmental Protection Division in Chapter 391-3-4 section .15 "Solid Waste Management" and Georgia Tech policy. The waste streams generated by biological laboratories should be separated into non-hazardous waste (trash), biohazardous waste, chemical waste, and radioactive waste.

A. General Definitions

1. Pathological Waste – This term refers to all recognizable human tissues and body parts except teeth which are removed during surgery, obstetrical procedures, autopsy, and laboratory procedures.

2. Biological Waste – This term means blood and blood products, exudates, secretions, suctioning, and other body fluids which contain free liquids and cannot be or are not directly discarded into a municipal sewer system.

3. Cultures and Stocks of Infectious Agents and Associated Biological – includes cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate and mix cultures.

4. Contaminated Mammalian Carcasses – includes body parts, the bedding and other wastes from mammalians which are infected with or have been exposed to infectious agents capable of causing disease in humans.

5. Sharps – this term means any discarded article that may cause punctures or cuts and has been exposed to infectious or potentially infectious agents, including humans and mammals. This waste includes, but is not limited to, items such as needles, IV tubing and syringes with needles attached, and scalpel blades.

6. Discarded Medical Equipment and Parts – not including expendable supplies and materials which have not been decontaminated, that were in contact with infectious agents.

B. Georgia Tech's Procedures for handling biomedical wastes on campus

1. Biomedical/biohazardous waste shall be segregated by separate containment from other waste at the point of generation. These wastes, except for sharps, are to be placed in orange or red plastic bags clearly identified with the universal biohazard symbol or clearly marked with the word "BIOHAZARD". The bags are to have strength sufficient to preclude ripping, tearing, or

bursting under normal conditions of use. The bag must then be placed into a biohazard cardboard box and properly marked with the Principal Investigator's name and laboratory number.

2. Contaminated Sharps (needles and syringes, Pasteur pipettes, etc.) must be placed in puncture proof and leak proof containers which are closed and transported to the autoclave for sterilization prior to disposal.

3. Broken glass may or may not be considered biomedical waste – glassware that has been contaminated with biohazardous agents must be decontaminated (autoclaving or chemical disinfection) prior to disposal with broken glass.

4. Contaminated combustible wastes and mammalian carcasses should be collected in leak proof closed containers. Clearly mark the biohazardous waste box with the appropriate classification of "animal carcass".

5. Human tissue can be disposed of two separate ways. If the human tissue is unrecognizable as a organ or body part, the tissue can be disposed of in a biohazardous waste bag and box. If the human tissue is an identifiable body part or organ, the PI must clearly mark on the box "human tissue". This segregates the waste for proper disposal by cremation or burial.

6. Liquid biohazardous materials are to be properly inactivated or sterilized prior to disposal in the community sewage treatment system. Methods for inactivation may be specific to the biohazardous agent contaminating the liquid.

7. Biomedical wastes may be treated so as to render items non-biomedical wastes. Biomedical wastes may be treated by autoclaving in a recording autoclave. Recording of the temperature during each complete cycle shall be used to assure the attainment of 121°C or 250°F for a minimum of 30 minutes in order to achieve decontamination of the entire load. Monitoring of the autoclave process through the use of biological or other approved indicators (i.e. autoclave tape, spore strips) is to be accomplished by the investigator and maintained along with the temperature recording as proof of decontamination. The PI must verify sterilization was successful before disposing of the treated waste.

   Several factors affect the steam sterilization process including load size, distribution and compaction, altitude above sea level; and heat penetration. The investigator or personnel responsible for sterilization may have to determine the appropriate time at standard autoclave temperature and pressure for certain loads of biohazardous materials. Barbeito and Gremillion in their article "Microbiological Safety Evaluation of an Industrial Refuse Incinerator" (Applied Microbiology 16:2:291-95) reported on various times required for autoclaving selected mammalian carcasses, mammalian bedding materials,

and eggs. With some loads, even extended times did not provide for sterilization.

Biomedical wastes may be treated by incineration in an incinerator which provides complete combustion of waste to render it nonpathogenic.

Autoclaved or incinerated waste may then be disposed of as nonregulated waste. The waste must be in a clear bag, with a visible biohazard designation. This clear bag, containing autoclaved waste must then be placed inside a non-biohazard cardboard box. It may then be disposed of as non-regulated waste. These measures are necessary to ensure that the waste will not appear to be biohazardous after it reaches the landfill.

Contact the Biosafety Officer in Environmental Health & Safety at 404/894-6119 regarding questions about the proper handling of biohazardous waste.

Contact the Hazardous Materials Officer in Environmental Health & Safety at 404/894-6224 regarding contract arrangements for pick-up and disposal of biomedical wastes including sharps.

C. Georgia Regulations

1. Georgia Department of Natural Resources/Environmental Protection Division – rules on solid waste management covering biomedical waste (391-3-4-.15) starting on page 77.

SECTION IV- CONTAINMENT OF BIOHAZARDOUS RESEARCH

Please see CDC/NIH – Biosafety in Microbiological and Biomedical Laboratories (BMBL). The BMBL can be found on the internet using the following link http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

Physical Containment of Experiments

Within each type of biohazard there are different degrees of risk which require different levels of containment. The term "containment" is used in describing safe methods for managing biohazardous agents in the laboratory environment where they are being handled or maintained. Primary containment, the protection of personnel and the immediate laboratory environment from exposure, is provided by good technique and the use of appropriate safety equipment that has been properly designed, located, installed, and maintained. Secondary containment, the protection of the environment external to the laboratory from exposure to biohazardous agents, is provided by a combination of facility design and operational practices. The three biosafety levels available at Georgia Tech are discussed below.

Biosafety Level 1 / Laboratory

Biosafety Level 1 (BSL 1) is suitable for working with agents having no known or minimal hazard to laboratory personnel and the environment (including plants and other animals). The laboratory practices and techniques, safety equipment, and physical facilities are those appropriate for undergraduate and secondary educational training and teaching. When assessing the risk of an experiment and determining the appropriate containment level it is important to remember that BSL 1 depends entirely upon good laboratory practice and using agents with no known hazards. The use of standard microbiological practice and techniques is basic for laboratory safety/containment; however, the PI must recognize that special precautions may be needed. The PI must ensure appropriate safety training for the BSL 1 laboratory and keep records of the training.

BSL 1 Standard Microbiological Safety Practices

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director. Limiting access to control the in/out traffic when experiments are in progress reduces sources of distraction and disturbance which may result in accidents. Closing laboratory doors during experiments is one method of controlling in/out traffic. This also allows for the exclusion of special category persons (children, immunosuppressed persons, etc) during times of potential exposure.

2. Work surfaces are decontaminated at a minimum at least once a day and immediately following any spill of viable material.

Contaminated equipment must be decontaminated according to any applicable local, state or federal regulations before it is sent for repair or maintenance or packaged for transport or surplused. This practice assists in the control of general contamination of the laboratory and reduces infection potential among laboratory personnel as well as repair people and others in contact with laboratory equipment.

3. All contaminated liquid and solid wastes must be decontaminated prior to disposal. Disposal of biomedical wastes shall be accomplished so as to comply with applicable local, state and federal laws and regulations; see Section III.

4. Mechanical pipetting devices are used; mouth pipetting is prohibited. Mechanical pipetting is easy and accurate, and prevents the ingestion of the materials being pipetted. [Several older publications referred to human infection and death associated with the mouth pipetting of pathogens.]

5. Eating, drinking, smoking, and the application of cosmetics shall be prohibited in any area where biohazards are present. Food may be stored in cabinets and refrigerators designated and used for this purpose only. Food storage cabinets and refrigerators shall be located outside the work area. Storage and/or consumption of food and drink and application of cosmetics in biohazardous work areas may result in exposure to laboratory personnel via the contamination of these products.

6. Personnel shall wash hands after handling viable materials and mammalians, after removing gloves, and before leaving the laboratory or mammalian facility. This practice reduces the potential for ingestion and/or adsorption of harmful microorganisms and hazardous chemicals. It also reduces the potential contamination of harmful microorganisms and hazardous chemicals to be transported between different projects in the same laboratory space, to other laboratories or facilities outside laboratory, or into the home.

7. All procedures using aerosols are performed carefully to minimize the creation of aerosols. Aerosols may be generated by several routine laboratory procedures and gain entry to lab personnel via inhalation, ingestion, and adsorption. Aerosols have been associated with many laboratory-acquired infections. They are, however, controllable with the use of safety procedures and containment equipment.

8. Personal protective equipment (PPE) shall be worn as appropriate when working with viable microorganisms, mammalians, and chemicals. Laboratory coats, gowns, uniforms, gloves, eye protection, etc. are examples of personal protective equipment. This procedure reduces the possibility of contaminating or soiling street clothing and carrying potentially hazardous agents out of the laboratory.

9. A biohazard sign must be posted at the entrance to the laboratory whenever infectious agents are present. The sign must include the name and phone number of the principal investigator.

10. An insect and rodent control program is in effect.

11. No special safety procedures are identified at BSL 1.

BSL 1 Laboratory Facilities

1. Laboratories should have doors for access control.

2. Each laboratory contains a sink for handwashing.

3. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.

4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surface and equipment.

5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.

6. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

7. Special containment equipment (i.e. biological safety cabinets) is not required.

Biosafety Level 2 / Laboratory

Biosafety Level 2 is suitable for work involving agents of moderate potential hazard to personnel and the environment (including plants and other mammalians). The practices, equipment, and laboratory design are appropriate for clinical, diagnostic, teaching, and basic research with a broad spectrum of

indigenous moderate-risk agents associated with human disease and/or which may negatively impact the environment. Laboratory procedures which generate aerosols may increase the risk and therefore are to be conducted in a biological safety cabinet and/or other primary containment equipment.

Biosafety Level 2 are those laboratories working with microorganisms, genetic materials, cell/tissue cultures, and carcinogens.

In addition to the BSL 1 Standard Microbiological Safety Procedures, the following Special Practices shall be implemented:

1. Access to the laboratory is limited or restricted by the laboratory supervisor when work with biohazardous agents is in progress. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or mammalian rooms. Keeping laboratory doors closed during experiments is recommended. Persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous shall not be allowed in the laboratory or mammalian rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections.

2. The principal investigator is responsible for providing training of laboratory personnel in the potential hazards and safety procedures. Knowledgeable personnel work more efficiently and effectively in the laboratory by reducing the risks of accidents that could result in personal injury or loss of research effort. [Georgia Law "Public Employee Hazardous Chemical Protection and Right to Know Act of 1988" (The Official Code of Georgia Annotated Title 45 Chapter 22) and the Department of Labor regulations (Chapter 300-3-19)] provide for training of employees using hazardous chemicals. It only makes sense that investigators also provide training to employees using biohazards.

3. When research involves working with or storing biohazardous agents in the laboratory, a hazard warning sign incorporating the universal biohazard symbol shall be posted on the access door. The principal investigator is ultimately responsible for informing persons, including emergency personnel, of any special requirement for entering the laboratory.

4. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container with a cover that

prevents leakage during collection, handling, processing, storage, transport, or shipping.

5. Before leaving the laboratory areas, protective clothing (lab coats, aprons, etc) shall be removed and left in the laboratory. This practice helps prevent infectious agents from being carried from the laboratory on contaminated clothing.

6. Animals not involved in the work being performed are not permitted in the laboratory.

7. Special care is taken to avoid contamination of skin and mucous membranes with infectious materials; appropriate personal protective equipment (gloves, goggles, face shield, etc) should be worn when handling infected mammalians or infectious materials.

8. Laboratory equipment and work surfaces should be decontaminated with an effective disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent to repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.

9. Spills and accidents which result in exposure of people or the environment to infectious materials and/or rDNA molecules shall be immediately reported to the principal investigator, to the biosafety officer at Environmental Health and Safety office.

10. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory, and periodic testing as recommended for the agent being handled.

11. When it is deemed appropriate by the principal investigator and/or the Institutional Biohazards and Biosafety Board, baseline serum samples for laboratory and other at-risk personnel shall be collected and stored at an approved non-institutional healthcare office. Additional samples may be collected periodically. Serum samples will be useful for biological monitoring of workplace exposures in the effort to reduce occupational risks. Stored serum samples are used only

to compare pre and post occupational exposure of serum components.

12. The principal investigator shall be required to develop standard operating procedures (SOPs) for the laboratory. Refer to page 19 in the IBBB manual for more information.

13. Laboratory personnel are to read and become familiar with the Institute Biosafety Manual and specific standard operating procedures (SOPs) of the laboratory. The principal investigator is responsible for providing supplemental safety training and information for personnel in his/her laboratory. Laboratory personnel shall be familiar with the NIH rDNA Guidelines and OSHA Bloodborne Pathogens and other applicable regulations regulations requiring appropriate biosafety training for laboratory personnel. Proper training reduces risk and promotes efficient research.

14. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids for laboratory mammalians and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.

    a. Only needle-locking syringes or disposable syringe-needle units (i.e. needle is integral to the syringe) should be used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather they must be carefully placed in puncture-resistant containers used for sharps disposal.

    b. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

    c. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps.

d. Disposal of biohazardous materials covered under the Georgia Environmental Protection Division regulations on Biomedical Wastes shall be accomplished according to those regulations.

BSL-2 Contaminated Equipment

Biological safety cabinets (BSC), preferably Class II, and other appropriate containment devices shall be to be used whenever laboratory procedures have a good potential for creating aerosols of infectious materials or rDNA molecules, or high concentrations or large volumes of infectious agents are used. Procedures that may create aerosols include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers, inoculating mammalians intranasally, and harvesting tissues from mammalians or eggs.

Biological safety cabinets and other containment devices shall be to be maintained in good working condition by the Principal Investigator. Certification of BSCs is to be accomplished annually or in the event that the BSC is moved or the HEPA filter is changed or major repair accomplished (whenever the contaminated plenum is breeched).

BSL-2 Laboratory Facilities

Laboratory facilities are similar to those for BSL-1 with the addition:

1. An autoclave (a recording autoclave is required for treating biomedical waste) which is readily available and easily accessible;
2. An eyewash station

Biosafety Level 3 / Laboratory

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious disease as a result of exposure by inhalation. A greater level of attention to microbiological practice, laboratory containment, safety equipment, and facilities is required.

All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.

The same standard practices as discussed for BSL-2 are appropriate for BSL-3 with the following additions/modifications:

1. Laboratory doors must be kept closed during experiments.

2. Included on the hazard warning sign posted on the laboratory access doors are special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

3. Protective clothing worn requires the closed front smock replacing the laboratory coat. All protective clothing shall be either disposed of in the laboratory or decontaminated by autoclaving prior to laundering.

BSL 3 Special Safety Practices

The same special practices which were appropriate for BSL-2 are appropriate for BSL-3 with the addition of:

1. All activities involving infectious materials or rDNA molecules from BSL-3 organisms shall be conducted using appropriate containment devices- Biological Safety Cabinets, safety centrifuge cups, etc. No work shall be/may be conducted in open vessels is conducted on the open bench. The significant reduction/prevention of exposure to aerosols is accomplished by a combination of safe work practices and containment equipment.

2. Decontamination of work surfaces is mandatory for both biosafety and quality control. However, special care is to be taken at BSL-3 due to the type of work being conducted. Spills of infectious material are to be handled immediately and properly. Refer to Section VII Spills of Biohazardous Materials. Contact the Institute Biosafety Officer at 404/894-6119. If chemicals are involved and the Biosafety Officer cannot be reached, contact the Chemical Safety Coordinator at 404/385-2964.

3. The need for and type of respiratory protection is based on the research being conducted. The investigator should discuss respiratory protection equipment with the Biosafety Officer.

4. Vacuum lines shall be protected with high efficiency particulate air (HEPA) filters and liquid disinfectant traps. These safety devices shall be routinely maintained and replaced as needed. The use of HEPA filters and traps helps prevent contamination of vacuum equipment and exposure of personnel who work on that equipment.

5. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility.

6. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

7. Respiratory and face protection are used when in rooms containing infected mammalians.

BSL 3 Containment Equipment

Biological safety cabinets and/or other physical containment equipment (e.g. centrifuge safety cups, sealed centrifuge rotors, and containment caging for mammalians) are necessary for all activities with infectious materials which pose a threat of aerosol exposure. Containment equipment may be augmented with specialized personal protective clothing. The types of procedures which may produce aerosol exposure include but are not limited to: laboratory manipulation of cultures or clinical and environmental samples which may contain infectious agents, aerosol challenge of experimental animals, harvesting of tissues or fluids from infected animals and embryonated eggs, and necropsy of infected mammals.

BSL 3 Laboratory Facilities

1. The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of doors is the required minimum requirement for entry into the high containment laboratory from access corridors or other contiguous areas. Doors are lockable. A clothes change room may be included in the passageway. Controlled access improves security for the containment laboratory and reduces air turbulence associated with the unrestricted movement of people.

2. Access doors to the high containment laboratory must be self-closing. This reduces the problem of forgetting to close doors to containment laboratories.

3. Each laboratory room contains a sink for handwashing. The sink is hands-free or automatically operated and is located near the room exit door.

4. The interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

4. Windows in the high containment laboratory are closed and sealed. Preferably, there must be double windows to prevent possible breach of containment in the case of window breakage.

5. A ducted exhaust air ventilation system must be provided in the high containment laboratory. The exhaust air shall not recirculated to any other area of the building and is dispersed away from occupied areas and air intakes. HEPA filtration and other ventilation is required and must be approved by the Biosafety Officer. This provides for a directional flow into the high containment laboratory. Since all work which may generate infectious aerosols is accomplished inside a biological safety cabinet or other containment device which filters exhaust air through HEPA filters, ambient laboratory air should not be contaminated.

6. The HEPA filtered exhaust air from a Class II biological safety cabinet is discharged directly to the outside via exhaust ducting or may be recirculated in the laboratory depending on the nature of the work being conducted, the investigator's history of maintaining containment equipment, and the approval of the Biosafety Officer. HEPA filters must be routinely maintained and certified to reduce the potential of exposure from leaks. Using an outside exhaust adds to the safety margin.

7. A method of decontaminating all laboratory waste is available in the laboratory (autoclave, incineration, chemical disinfection, or other approved method).

8. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory air.

Operation of Laboratory Equipment

Georgia Tech personnel should not operate equipment that they have not been specifically trained and authorized to use. Operating manuals must be onsite and consulted or detailed operating instructions for individual pieces of equipment.

Equipment known or suspected of being faulty should not be operated. Mechanically or electrically unsafe equipment should be tagged and reported to the laboratory supervisor.

Autoclave/Steam Sterilizers

Moist heat, in the form of steam under pressure, is the most dependable medium for the destruction of all forms of microbial life. Autoclaves are instruments which produce superheated steam under high pressure and are used for two processes decontamination and sterilization.

Autoclave loads should be routinely checked with appropriate indicators to the adequacy of the sterilization or decontamination (for biomedical waste) processes. Barbeito and Gremillion in their article "Microbiological Safety Evaluation of an Industrial refuse Incinerator" (Applied Microbiology 16:2:291-95) reported on various times required for autoclaving selected mammalian carcasses, mammalian bedding materials, and eggs. With some loads even extended times did not provide for sterilization. Investigators or personnel responsible for sterilization may have to determine appropriate times and maintain appropriate records of the process.

Autoclaves should receive routine inspection to determine the need for maintenance and repair. Autoclave door gaskets may become distorted if the door is tightly shut for prolonged periods resulting in leaks. Doors should be kept open or loosely closed except when the autoclave serves as a barrier between clean and dirty areas.

Effective decontamination and sterilization by steam depends on the adequacy of circulation of the steam; loads packed tightly may not allow for adequate circulation. The steam must penetrate all packaging materials and contact all surfaces to be decontaminated or sterilized. And, finally the packaging must prevent the recontamination of the sterilized materials. To achieve effective and safe use of the autoclave the laboratory personnel must be familiar with and follow the laboratory's procedures regarding:

1. Types of packaging – autoclavable pan, bag in pan, double bag, etc.
2. Separating into pans/bags for autoclaving in the lab
3. Adding water/germicidal solutions – Do not autoclave radioisotopes or explosive or volatile chemicals without checking with radiation safety, laboratory safety and biological safety.
4. Use specific autoclaves – "dirty" autoclaves for decontamination and "clean" autoclaves for sterilization and biological media.

5. Proper settings for type of cycle, and type and amount of material. Details of proper operation and settings may be contained in the specific device operation manual. Monitor the autoclave process for proper cycle and length of time. Cycle and time depend on what is being sterilized. For example, liquids would require the use of slow exhaust and while most loads require cycle times of 15 to 30 minutes at 121°C, longer times may be needed to meet the thermodynamic needs of special loads. The decontamination of biomedical waste may regularly require 60 minutes at 121°C.
6. When the cycle is completed care must be taken to wear proper personal protective equipment and to use proper unloading procedures. These include: personal protective equipment - laboratory coat and apron that resists liquid (i.e. rubber/plastic) gloves that are heat and liquid resistive, and goggles and/or face shield. Procedures - Stand away from the autoclave door when opening to avoid a rush of steam and open slowly; do not move boiling liquids; and allow sufficient cooling time before handling superheated solution (i.e. microbiological culture media) to avoid burns and exploding glass.
7. Spill clean-up procedures should be posted in every autoclave room and followed when a spill occurs.

Biohazard Containment Equipment

Many manipulations of bacterial and viral cultures commonly used in the laboratory generate aerosols of viable organisms. This principle must be remembered when evaluating a person's degree of risk.

Biological Safety Cabinets

Primary biohazard containment devices serve to protect laboratory personnel from exposure to infectious aerosols produced by routine procedures. The biological safety cabinet (laminar flow hood) can be an extremely usefully containment device for both personnel and product protection.

Before purchasing a biological safety cabinet, horizontal flow clean bench or a vertical flow clean bench must be approved by the Biosafety Officer. After installation, the principal investigator must then contact a contractor (example Dixie Filters, Inc 1-800-344-0050) to inspect and certify the biological safety cabinet, horizontal flow clean bench, or vertical flow clean bench annually. The Biosafety Officer must have a copy of the certification to keep on file in the EH&S office.

The Biosafety Officer will keep records on all Laminar Flow Hoods and Biological Safety Cabinets.

Centrifuges

Centrifuges are an important tool in the microbiological laboratory and must be treated with respect. Each time you use a centrifuge you make a series of choices: Which centrifuge, which rotor, which tubes and adapters, what speed and for how long. In addition, if you are using infectious agents you must decide on the level of containment and then select the appropriate rotor and tubes. Load the infectious agents inside the biological safety cabinet to prevent aerosol exposure. Your choices will affect your research and the safety of you and others.

Always check the user manual for specific requirements as well as load limitations and speed. Specific operating procedures for each centrifuge must be established by the laboratory supervisor or principal investigator and followed by each operator. These procedures should follow the information provided in the operation manual and guidelines for centrifugation of infectious agents, chemical hazards and/or radioactive materials. Make sure the load is properly balanced – a minor error may not be a problem at low speed but may be serious at higher speeds.

Centrifuge tubes must be selected with the knowledge of the materials they will contain and the pressures they will be under. Plastic centrifuge tubes should be used whenever possible to minimize breakage. Nitrocellulose tubes should only be used when clear, without discoloration, and flexible so that tubes are maintained in good working condition. It is advisable to purchase small lots several times a year rather than one large lot. The nitrocellulose tubes should be stored at 4°C to extend the shelf life. Nitrocellulose tubes must not be used in angle-head centrifuges.

Tubes to be used in angle-head centrifuges must never be filled to the point that the liquid is in contact with the lip of the tube when it is placed in the rotor, even though the meniscus will be vertical during rotation. When the tube lip is wetted, high G force drives the liquid past the cap seal and over the outside of the tube.

Inspect all centrifuge tubes prior to use. Broken, cracked, or damaged tubes must be discarded.

Capped centrifuge tubes should be used whenever possible.

Carrier Cups and Rotors

It has been estimated that 80% of centrifuge accidents are operator error. The most common operator errors are: (1) Failure to secure the rotor to the drive shaft; (2) Failure to place lid on the rotor; and (3) Failure to secure the lid. Additionally, it is very important not to run the rotor above its rated maximum and not to overfill it.

Cryogenic Liquids

Cryogenic liquids are gases that have been transformed into extremely cold refrigerated liquids, which are stored at temperatures below minus 90°C. They are normally stored at low pressures in specially constructed multi-walled, vacuum-insulated containers.

The hazard potential presented by cryogenic liquids may result from the extreme cold, and pressure, which can result from rapid vaporization, and asphyxiation due to the displacement of air.

Appropriate personal protective equipment (heavy leather gloves/gloves for extreme cold, safety shoes, aprons, and eye protection) must be worn when handling cryogenic liquids or materials preserved in cryogenic liquids.

Lasers

Lasers are a tool of biological research and as such must be used in accordance with applicable safety precautions. Refer to Debbie Wolfe-Lopez, of Georgia Tech's EH&S, at 404/385-2964 for appropriate guidance in laser safety.

Ultra Violet Light

Under certain conditions of radiation intensity and exposure time UV radiation may kill certain types of microorganisms. Its greatest effect is against vegetative forms. UV is not a sterilizing agent except in certain exceptional circumstances. It is used to reduce the numbers of microorganisms on surfaces and in the air. The age of the UV lamp, dust accumulations on the bulb, and other factors that impede direct contact of the UV on the microorganisms contribute to decreased efficacy.

Contact Debbie Wolfe-Lopez, of Georgia Tech's EH&S, at 404/385-2964 for additional information and safety requirements.

Microwave Ovens

Microwave ovens used in the laboratory for research may not be used to heat food.

When melting agar the following precautions must be taken to prevent explosions: caps on screw-cap bottles must be completely loosened before heating the bottles in the microwave, and the operator must wear appropriate personal protective equipment including laboratory coat or apron, heat resistant gloves, and face shield.

Laboratory Vacuum Lines

When a laboratory vacuum is used to manipulate biohazard materials, suitable filters and traps are to be used to prevent contamination of the vacuum lines and pumps. Vacuum lines may need a HEPA filter depending on the laboratory setting.

Repair and Maintenance of Equipment and Facilities and New Construction

Institute employees or outside vendors undertaking facility expansion, equipment repair and maintenance, and general maintenance activities should not be unnecessarily exposed to biological hazards.

New Construction and Renovation – It is expected that new construction and renovation projects involving biohazard laboratories are to be reviewed in the planning stages by the Environmental Health & Safety department, in cooperation with Physical Plant, Campus Planning, and other campus support groups.

Repair and Preventive Maintenance – repair or routine preventive maintenance of mechanical or laboratory equipment in posted biohazard areas is not to be initiated from the Biosafety Officer.

Removal of equipment – Potentially contaminated equipment is not to be removed from biohazard laboratories for repair, servicing, cleaning or to surplus properties or repair shops or other areas until decontamination and removal of biohazard labels have been performed. The investigator or laboratory supervisor is to certify such equipment as being free of biohazard agents. Service personnel may ask laboratory personnel to sign a certification statement that the decontamination procedure was performed.

Biosafety level 3 agents should not be handled when service personnel are in the laboratory to minimize potential exposure to them.

Vertebrate Animal Biosafety Criteria – Selected Aspects

The Institute's policy on the Care and Use of Laboratory Animals can be found in the Georgia Institute of Technology Animal Care and Use Committee's publication of Policies and Procedures, dated February 2003.

These are posted to the Office of Research Compliance website at http://www.osp.gatech.edu/compliance/animals/gatechiacuc.pdf.

SECTION V- INFECTIOUS AGENTS- BIOSAFETY LEVEL

The four biosafety levels for containment purposes and the types of agents placed in them are:

Biosafety Level 1 (BSL 1)– suitable for work involving agents of no known or of minimal potential hazard to laboratory personnel and the environment.

Biosafety Level 2 (BSL 2)– suitable for work involving agents of moderate potential hazard to personnel and the environment. Agents which may produce disease of varying degrees of severity from exposure by injection, ingestion, adsorption, and inhalation, but which are contained by good laboratory techniques are included in this level. Any agent from outside of Georgia which may require a state or federal permit for importation are to be contained at BSL-2 or greater.

Biosafety Level 3 (BSL 3)– applicable to clinical, diagnostic, teaching, and research or production facilities involving indigenous or exotic agents or exotic strains of indigenous agents which may cause serious or potentially lethal disease as a result of exposure by inhalation. Autoinoculation and ingestion also represent major hazards to personnel working with agents in this classification. A greater level of attention to microbiological practices, laboratory containment and safety equipment, and facilities is required.

Biosafety Level 4 (BSL 4)– required for work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. There are currently no BSL-4 approved facilities at Georgia Institute of Technology at this time.

Note: Vaccine strains which have undergone multiple in vivo passages should not be considered avirulent simply because they are vaccine strains.

SECTION VI- BLOODBORNE PATHOGENS

Universal Blood and Body Fluid Precautions

The following are the key elements which must be used at Georgia Institute of Technology to control occupational exposures to bloodborne pathogens when working with human and/or mammalian blood or bodily fluids. All blood and body fluids must be considered as potentially infectious and personnel are to use appropriate protective measures to prevent exposure.

Personnel Practices

Hand-washing:

- When hands become contaminated with blood or body fluids
- When gloves are removed after working with biologicals
- Before going to lunch, breaks, or home

Contaminated Needles and Other Sharps:

- DO NOT recap, bend, or break used needles
- Discard needles & sharps in appropriate "Sharps" containers
- Transport reusable sharps in leak-proof puncture-resistant container
- Use mechanical device (forceps) to place contaminated broken glass into appropriate containers for autoclaving

Personal Protective Equipment for Blood or Body Fluid Contact

- Gloves when touching blood or body fluids, mucous membranes, or infected skin of patients
- Gloves when handling items or surfaces soiled with blood or body fluids
- Gloves when performing vascular access procedures (phlebotomy)
- Appropriate gowns or aprons when splashes or soiling of skin or clothing with blood or body fluids is likely
- Masks and goggles, or face shield during procedures likely to generate splashes of blood or body fluids into the mouth, nose, or eye

Environmental Controls

General Housekeeping:

- Maintain work area in clean and sanitary condition
- Decontaminate work surfaces after procedures and when contaminated
- Remove any protective work surface coverings when contaminated

Blood or Body Fluid Spills:

- Soak up spills with absorbent material (paper towels)
- Decontaminate area with appropriate disinfectant
- Dispose of contaminated material appropriately

Biomedical Wastes:

- Are to be disposed of according to State of Georgia Regulations.
- Refer to Section III-Biohazardous Waste Disposal

Transport:

- Consider all laboratory specimens of human or mammalian origin as potentially infectious
- Use leak proof containers for laboratory specimens
- Place container in a sealable secondary container for transport

Exposure to blood or body fluids via broken skin or needle sticks or mucous membrane contact:

- Wash affected area immediately and apply first aid
- If the injury is serious, call 9-1-1, then call campus police at 404/894-2500 to inform them of the situation.
- If a student, contact Health Services as soon as possible for post exposure follow-up. If faculty/staff, contact your non-institute doctor's office as soon as possible for post exposure follow-up.
- Report injury to the Biosafety Officer at 404/894-6119

SECTION VII- OTHER ORGANISMS

Individuals using any infectious/poisonous plant or animal pathogens (other than mammals) need to coordinate their laboratory activities with the Institutional Biosafety and Biohazards Board (IBBB).

Individuals working with vertebrate animals need to coordinate their laboratory activities with the Institutional Animal Care & Use Committee (IACUC).

Individuals working with human subjects need to coordinate their laboratory activities with the Institutional Review Board (IRB) Human Subjects Research.

SECTION VIII- SPILLS OF BIOHAZARDOUS MATERIALS

Primary responsibility for preventing and/or containing and cleaning up laboratory spills remains with the principal investigator or laboratory supervisor. Laboratory protocols should be carefully designed to prevent biological, chemical and/or radiation spills.

When accidents occur that involve the mishandling or escape of biohazardous materials, the principal investigator or laboratory supervisor is to be notified immediately. Spills of high risk organisms (certain Class 2 and all Class 3) should be reported to the Biosafety Officer at 404/894-6119 during normal working hours or to Georgia Tech Police at 404/894-2500 after normal working hours by the principal investigator or laboratory supervisor. All employees and/or students have an obligation to themselves and their colleagues to report accidents immediately in order to minimize potential hazards.

When a biohazardous spill also involves radioactivity, cleanup procedures may have to be modified. The extent of the modification will depend on the level of radiation and the nature of the isotope involved. The Radiation Safety Officer should be called during normal working hours at 404/894-3600, or Georgia Tech police should be called after working hours at 404/894-2500.

The following guidelines must be followed by the principal investigator, laboratory supervisor, and other responsible individuals who may be involved in the cleanup of biological spills.

Biohazard Spills inside Laminar Flow Biological Safety Cabinets (LFBSC)

The occurrence of a spill in the biological safety cabinet poses less of a problem than a spill in an open laboratory as long as the spilled materials are contained in the biological safety cabinet. Decontamination of the work zone can be effected by direct application of concentrated liquid disinfectants along with a thorough wipe down procedure. Gaseous decontamination may be required to clean-up the interior sections of the cabinet.

4. Chemical decontamination procedure should be initiated immediately while the biological safety cabinet continues to operate. Continuing the operation of the LFBSC helps to prevent the escape of contaminants from the cabinet.
5. Wearing protective gloves, safety glasses, a lab coat/apron, and at a minimum a surgical mask, spray or wipe walls, work surfaces, and equipment with an appropriate decontaminating solution. A disinfectant detergent, such as Wescodyne or Environ has the advantage of detergent action on extraneous organic substances which may interfere with the microbicidal activity of the disinfectant.
6. Flood tray top, drain pans, and catch basins below work surface with decontaminating solution and allow to stand for 20 minutes.
7. Drain excess decontaminating solution from tray and drain pans into cabinet base. Lift out tray and removable exhaust grille work. Clean the

top and bottom (underside) surfaces using a sponge or clean cloth soaked in decontaminant solution. Following the cleaning process, replace the tray and grille work in their proper position. Place gloves and sponge or cloth in autoclave pan and autoclave these items.

8. Drain decontaminating solution from cabinet base into appropriate container and autoclave according to standard procedures.
9. If gaseous decontamination of the cabinet's interior sections is needed, call the Biosafety Officer at 404/894-6119.
10. For skin contamination, refer to Appendix H- First Aid.

Biohazard Spills Outside Laminar Flow Biological Safety Cabinets (LFBSC)

The protocol to be used in cleaning up of spills involving microorganisms will depend on the amount of material spilled and the degree of laboratory containment required.

If individuals believe that their outer garments have been contaminated, they should remove their clothing in the laboratory area and place them in an autoclave or a container for autoclaving. They should change into clean clothing in a non-contaminated area. All laboratory personnel should keep a complete change of clothing, including shoes at the laboratory in case of spills.

Special care in decontamination will be necessary when a spill goes under or between fixed furniture or behind base moldings (floor/wall), or if floor penetrations are involved.

For skin contamination, refer to Appendix H- First Aid.

1. **Minor Spills (less than 10 ml and generating little aerosol) on equipment, laboratory benches, walls, or floors**:
    a. Warn all personnel not essential for spill containment to stay clear of the contaminated area. This may be accomplished verbally or, when appropriate, by posting warning signs on the doors.
    b. Thoroughly wash hands and other apparently contaminated areas with soap and water. Put on clean disposable gloves.
    c. Cover the spill area with paper towels soaked in appropriate decontamination solution.
    d. Wipe up the spill with the soaked paper towels and place the used towels in an autoclave pan and autoclave.
    e. Pour decontaminating solution around and on the area of the spill. Let stand for 20 minutes then wipe up with paper towels. Place gloves and paper towels in autoclave pan and autoclave.
    f. Wash hands and other apparently contaminated areas again with soap and water.

2. **Major Spills (more than 10 ml or with considerable aerosol):**
    a. Close laboratory doors and post warning signs to prevent others from entering the laboratory.
    b. Wash hands and other apparently contaminated areas with soap and water.
    c. Report the accident to the supervisor and to the Biosafety Officer at 404/894-6119.
    d. If personal clothing is contaminated, remove all outer clothing and place it in autoclave or container for autoclaving. Put on clean garments.
    e. Leave the laboratory for 20 minutes to allow dissipation of aerosols created by the spill.
    f. Upon returning to the laboratory to start decontamination, check to see if laboratory doors are closed and appropriate signs are displayed. Put on surgical gloves. Respirators or other safety equipment may be required, depending on the microorganism involved. Check with the Principal Investigator or Laboratory Supervisor or Biosafety Officer.
    g. Pour a decontamination solution around the spill and allow this solution to flow into the spill. Paper towels soaked with decontamination solution may be used to cover the area. Do not pour decontamination solution directly onto the spill in order to avoid additional release of aerosols.
    h. Let decontamination solution – microorganism mixture stand for 20 minutes or longer to allow adequate contact time.
    i. Using autoclaved dust pan and squeegee transfer all contaminated materials to deep autoclave pan, cover with suitable cover, and autoclave according to standard directions.
    j. Place dust pan squeegee in an autoclavable bag and autoclave according to standard directions.
    k. Remove gloves and other contaminated garments and place them in an autoclave container for autoclaving.
    l. Thoroughly wash hands, face, and other potentially contaminated areas.

Special care in decontamination may be necessary. The Principal Investigator and/or Biosafety Officer may require the collection of sample cultures to determine that the area has been effectively decontaminated.

Liquid Disinfectants

Laboratory personnel should be familiar with the various disinfectants that will effectively kill the biohazardous agents being used. The following information is provided to assist in your selection of appropriate disinfectants.

Alcohols – Ethyl and Isopropyl are good disinfectants for the vegetative forms of bacteria and lipoviruses.

Ethyl Alcohol

Use Dilution: 70-95%

Inactivates: vegetative bacteria and lipoviruses, has variable results with non-lipoviruses and is ineffective with bacterial spores.

Other Characteristics: flammable, eye irritant, and an upper respiratory tract irritant (TLV = 1000ppm)

Isopropyl Alcohol

Other Characteristics: Flammable, CNS depressant, narcotic and irritating to mucous membranes (TLV = 200 ppm)

Chlorine Compounds – The germicidal effect of chlorine compounds is dependent upon the release of hypochlorous acid and is therefore dependent upon the available chlorine. Allow a contact time of 10 to 30 minutes.

Use Dilution: 500 ppm available chlorine is recommended for vegetative bacteria and most viruses. Chlorine solutions that are neutral or slightly acidic and with a concentration of approximately 2500 ppm are needed for effectiveness against bacterial spores. Undiluted common household bleach (Chlorox) is alkaline with a pH of 8. Household bleach typically contains 5.25% sodium hypochlorite.

Other Characteristics: Chlorine compounds are corrosive to metals; leave a residue; irritate the skin, eyes, and respiratory tract; and are toxic. Chlorine compounds are also rapidly inactivated by organic matter. While chlorine compounds are not generally recommended for routine use, undiluted household bleach is frequently used with biological spills.

Iodophors: The germicidal effect of iodophors is dependent on the free iodine released from the compound in which it is contained. Allow a contact time of 10 to 30 minutes.

Use Dilution: 25 to 1600 ppm of available iodine. Solutions containing 75 to 150 ppm are generally recommended.

Inactivates: vegetative bacteria, fungi and viruses. There is poor activity against bacterial spores.

Other Characteristics: Although iodophors are less harmful to man than chlorine compounds, they can irritate the skin and eyes. Iodophors are corrosive (less than

chlorine), they leave a residue and may stain. Iodophor stains, however, can be readily removed with solutions of sodium thiosulfate ($Na_2S_2O_3$). As with the chlorine compounds, iodophors are rapidly inactivated by organic matter. One advantage is that iodophors have a built-in indicator. As long as the solution is brown or yellow it is still active.

Phenolic Compounds: These are effective against vegetative bacteria (including mycobacterium tuberculosis), fungi, and lipoviruses. Effectiveness against non-lipid viruses is variable depending on the virus. The phenols are ineffective against bacterial spores.

Use Dilutions: 1.0 – 5.0% solutions containing 0.5 – 2.0 % phenol are effective against lipoviruses.

Other Characteristics: Phenols are corrosive and may leave a sticky, gummy residue. Phenolic compounds are irritating to the skin and eyes and the cardiovascular, hepatic, renal, and neurological toxicity. – Phenol TLV is 5 ppm; it can be readily absorbed through the skin.

Quaternary Ammonium Compounds: The efficacy of Quaternary Ammonium (quats) still generates considerable controversy. Quats are effective in destroying ordinary vegetative bacteria and lipid containing virus but are not effective against pseudomonas, proteus, and other gram-negative bacilli. Also, Quats are not effective against spores at the usual use concentrations of 1:750.

Use Dilutions: 0.1 to 2.0%

Other Characteristics: Quats are surface-active compounds which posses the useful property of lowering the surface tension of the solution. Other advantages include being nontoxic, odorless, non-staining, non-corrosive to metals and stable. If used at recommended concentrations, Quats are nonirritating.

Quaternary Ammonium compounds are rapidly inactivated by organic matter.

Formaldehyde Solutions: Formaldehyde in a 5-8% concentration is an effective liquid decontaminant which inactivates vegetative bacteria, bacterial spores, lipid and non-lipid viruses and fungi.

Use Dilution: 5.0-8.0%

Other Characteristics: Formaldehyde TLV established to minimize sensory irritation, chiefly eye and upper respiratory tract. Formaldehyde is a sensitizer and a suspected human carcinogen. TLV is set at 0.3 ppm ceiling, but this TLV might not be protective to sensitized individuals.

Section XI- Material Transfer Initiation Information for Transfer of Biological Materials

Whenever Georgia Tech employees intend to exchange chemical, biohazardous, biological materials (including select agents), or proprietary material with another organization (academic or commercial), the arrangements, terms, and conditions must be formally covered under a Material Transfer Agreement (MTA). An MTA identifies the materials being exchanged and documents the terms of the exchange, including intellectual property rights, liability issues, publication, confidentiality, royalties and other financial terms. MTAs are agreements between institutions, not individuals, and they may be complex. The material-transfer agreement will provide an assurance that the person receiving the material will not give it to anyone else, and that they cannot commercialize the material.

At Georgia Tech, the process for exchanging the materials begins with the MTA initiation form which must be signed by the Principal Investigator and department head; the Associate Vice-Provost for Research and General Manager of GTRC gives final approval (and is the person who can commit the organization to the terms of the agreement). Intellectual Property terms are reviewed by the Office of Technology Licensing, and additional approvals may be required from the Institutional Review Board, the Institutional Animal Care & Use Committee, and/or the Institutional Biosafety and Biohazards Board. The Office of Sponsored Programs/ReACTT will assist with MTA preparation, negotiation, and administration.

If materials are being transferred to Georgia Tech, the other organization will likely provide its own MTA agreement. You will still need to complete the Georgia Tech Materials Transfer Initiation Form and forward it to Michelle Joy Clark, Office of Sponsored Programs/ReACTT, Mail Code 0420, along with the other organization's paperwork. For outgoing materials, the process is the same, except the Georgia Tech Principal Investigator should generate the Materials Transfer Initiation Form and forward it the same way.

Please note: In either scenario, the agreement is executed on behalf of Georgia Tech Research Corporation rather than the Georgia Institute of Technology.

The Materials Transfer Initiation Form for requesting approval of a material transfer (incoming or outgoing) may be found on the Sponsored Programs website at http://www.osp.gatech.edu/forms.htm. For assistance, contact Michelle Clark at 404 / 894-6945, michelle.clark@osp.gatech.edu, or Barbara S. Henry at 404 / 894-6949, barbara.henry@osp.gatech.edu.

A copy of the Material Transfer Initiation Form is located in Appendix I. The form can also be obtained at www.osp.gatech.edu/forms/MTA_GaTech.doc

With gratitude to University of Georgia for sharing its policies and procedures.

APPENDIX A

BIOSAFETY SIGN

APPENDIX B

General Guidelines for covered rDNA Projects

General guidelines for covered rDNA projects can be found at:

http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

APPENDIX C

Shipping of Infectious Agents

- **Guidelines for the Shipment of Dried Blood Spot Specimens: www.cdc.gov/od/ohs/biosfty/driblood.htm**
- **Interstate Shipment of Etiologic Agents: www.cdc.gov/odohs/biosfty/shipregs.htm**
- **Packaging and Shipping Instructions for Biomedical Material: www.cdc.gov/od/ohs/biosfty/shipdir/htm**
- **USDA APHIS forms: www.aphis.usda.gov/forms/index.html**
- **USDA APHIS Import-Export Manual**:
- www.aphis.usda.gov/ppq/manuals/pdf_files/ECM.pdf
- **U.S. Department of Transportation: www.dot.gov**
- **U.S. Department of Commerce, Bureau of Export Administration: www.bxa.doc.gov**
- **U.S. Postal Service, domestic Mail Manual (DMM), mailability of Etiologic Agents: pe.usps.gov**
- **International Air Transport Association (IATA), Dangerous Goods Regulations: www.iata.org/index.htm**

APPENDIX D
Certification of Training

By my signature below, I certify that I have read the Biosafety Manual and the Laboratory Security Procedures for working with the following agent(s)
☐ select agent ☐ infectious agent

List the agents you are have been authorized to work with:

_____

_____

_____

_____

_____

_____

_____

_____

I further certify that I have been informed the hazards of working with the above listed agents; the indications of infection or intoxication by this/these agent(s); the reporting system for potential exposure and accidents; how to seek evaluation and therapy; the standard microbiological practices for this laboratory; the special biosafety practices required for biosafety level 1 2 3 4 (circle one) work; and the standard operating procedures for this laboratory.

*Send a signed copy to the Biosafety Officer in EH&S, mail code 0465

_____
Printed Name

_____
Signature

_____
Date

APPENDIX E
Select Agent List

HHS NON-OVERLAP SELECT AGENTS &TOXINS

Crimean-Congo haemorrhagic fever virus
Coccidioides posadasii
Ebola viruses
Cercopithecine herpesvirus 1 (Herpes B virus)
Lassa fever virus
Marburg virus
Monkeypox virus
Rickettsia prowazekii
Rickettsia rickettsii

South American haemorrhagic fever :viruses
Junin
Machupo
Sabia
Flexal
Guanarito

Tick-borne encephalitis complex (flavi) viruses:
Central European tick-borne encephalitis
Far Eastern tick-borne encephalitis
Russian spring and summer encephalitis
Kyasanur forest disease
Omsk hemorrhagic fever

Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)
Yersinia pestis
Abrin
Conotoxins
Ricin
Saxitoxin
Shiga-like ribosome inactivating proteins
Tetrodotoxin

HIGH CONSEQUENCE LIVESTOCK PATHOGENS & TOXINS/SELECT AGENT (OVERLAP AGENTS)

Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly Pseudomonas mallei)
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei*)
Botulinum neurotoxin producing species of *Clostridium*
Coccidioides immitis
Coxiella burnetii
Eastern equine encephalitis virus
Hendra virus
Francisella tularensis
Nipah Viru
Rift Valley fever virus
Venezuelan equine encephalitis virus
Botulinum neurotoxin
Clostridium perfringens epsilon toxin
Shigatoxin
Staphylococcal enterotoxin
T-2 toxin

USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS & TOXINS (NON-OVERLAP AGENTS & TOXINS)

Akabane virus
African swine fever virus
African horse sickness virus
Avian influenza virus (highly pathogenic)
Blue tongue virus (Exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Cowdria ruminantium (Heartwater)
Foot and mouth disease virus
Goat pox virus
Lumpy skin disease virus
Japanese encephalitis virus
Malignant catarrhal fever virus (Exotic)
Menangle virus
Mycoplasma capricolum/M.F38/M. mycoides capri
Mycoplasma mycoides mycoides
Newcastle disease virus (VVND)
Peste Des Petits Ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (Exotic)

LISTED PLANT PATHOGENS

Liberobacter africanus
Liberobacter asiaticus
Peronosclerospora philippinensis
Phakopsora pachyrhizi
Plum Pox Potyvirus
Ralstonia solanacearum race 3, biovar 2
Schlerophthora rayssiae var *zeae*
Synchytrium endobioticum

Xanthomonas oryzae
Xylella fastidiosa (citrus variegated chlorosis strain)

APPENDIX F

Select Agent Access

The following individuals have been granted access to the locked freezers, refrigerators, cabinets, and other containers where stocks of select agents are stored.

Authorized Person	Authorized Access	Authorized by:

APPENDIX G

Integrated Pest Management

Pest management is an important part of managing a research facility. Many pests, such as flies and cockroaches, can mechanically vector disease pathogens and compromise the research environment. Even the presence of innocuous insects can contribute to the perception of unsanitary conditions.

The most common approach to pest control has been the application of pesticides, either as a preventive or remedial measure. Pesticidal treatments can be effective and may be necessary as a corrective measure, but they have limited long-term effect when used alone. Pesticidal applications also present the potential to contaminate the research environment through pesticide drift and volatilization.

To control pests and minimize the use of pesticides, it is necessary to employ a comprehensive program approach to pest management that integrates housekeeping, maintenance, and pest control services. This method of pest control is often referred to as Integrated Pest Management (IPM). The primary goal of an IPM program is to prevent pest problems by managing the facility environment in such a way as to make it less conducive to pest infestation. Along with limited applications of pesticides to control pests, pest control is achieved through proactive operational and administrative intervention strategies to correct conditions that foster pest problems.

IPM is a strategy-based service. The decision to implement an IPM program should be based not only on the cost of the services, but on the effectiveness of the program's components. IPM is site-specific, and each program should be tailored to the environment where it is applied. IPM services in a laboratory will be different from those in an office building or an animal care facility.

Integrated pest management programs can be delineated into various interrelated components which contribute to the environmental management" approach to controlling pests. These are:

- *Facility Design:* The inclusion of pest management issues and requirements in a facility's planning, design, and construction provides an opportunity to incorporate features that help to exclude pests, minimize pest habitat, and promote proper sanitation. This can help to reduce the need for future corrective pest management services that can be disruptive to research operations.
- *Monitoring:* Traps, visual inspections, and staff interviews are used to identify areas and conditions that may foster pest activity. Monitoring is the central activity of an IPM program and is used in place of preventive Pesticidal treatments.
- *Sanitation and Facility Maintenance:* Many pest problems can be prevented or corrected by using proper sanitation, reducing clutter and pest habitat, and by performing repairs that exclude pests and reduce pest habitat. Maintaining

records of structural deficiencies and housekeeping conditions can help to track problems and determine if corrective actions are completed in a timely manner.

- *Communications:* A staff member can be designated to meet with pest management personnel to assist in resolving facility issues that impact on pest management. Information on pest activity, and recommendations on personnel practices and facility conditions that impact pest management, can be relayed verbally and in writing to that person. Training on subjects such as pest identification, biology, and sanitation can also promote understanding and cooperation with the goals of the IPM program.
- *Record Keeping:* A logbook can be used to record pest activity and conditions pertinent to the IPM program. It may contain protocols and procedures for IPM services in that facility; Material Safety Data Sheets on pesticides; pesticide labels; treatment records; floor plans; survey reports; etc.
- *Nonpesticidal Pest Control:* Pest control methods such as trapping, exclusion, caulking, washing, and freezing can be applied safely and effectively when used in conjunction with proper sanitation and structural repair.
- *Pest Control With Pesticides:* Preventive applications of pesticides should be discouraged, and treatment should be restricted to areas of known pest activity. When pesticides are applied, the least toxic product(s) available should be used and applied in the most effective and safe manner.
- *Program Evaluation and Quality Assurance:* Quality assurance and program review should be performed to provide an objective, ongoing evaluation of IPM activities and effectiveness. This is to ensure that the program is controlling pests and meeting the specific needs of the facility program(s) and its occupants. Based upon this review, current pest management protocols can be modified and new procedures implemented.
- *Technical Expertise:* A qualified entomologist can provide helpful technical guidance in developing and implementing an IPM program. Pest management personnel should be licensed and certified through examination by the appropriate regulatory agency.
- *Safety:* By limiting the scope of Pesticidal treatments and using nonpesticidal control practices, IPM can minimize the potential of pesticide exposure to the research environment and the staff.

Prior to initiating any type of pest management program, develment of an operational framework for IPM services can help to promote collaborationi between pest management specialists and facility personnel. This framework can also be used to incorporate facility restrictions and operational and procedural issues into the IPM program. An effective pest management program is an integral part of the facility's management. Including an IPM policy statement in the facility's standard operating procedures can increase awareness of the program.

Training on the principles and practices of structural (indoor) intergrated pest management and information on IPM programs is available from many sources. Some of these are Institute entomology departments, county extension offices, the

Entomological Society of America, state departments of agriculture, state pest control associations, the National Pest Control Association, suppliers of pest control equipment, and pest management consultants or pest management firms. There are also correspondence courses available from several universities as well as short courses and training conferences on structural pest management.

Additional Information:

Urban Entomology. 1996. Insect and Mite pests in the Human Environment. W. H. Robinson. Chapman and Hall. New York.

Advances in Urban Pest Management. 1986. Gary W. Bennett and John M. Owens, eds. Van Nostrand Reinhold Company. New York

Common Sense Pest Control. 1991. Least-toxic solutions for your home, garden, pests and community. William Olkowski, Sheila Daar, Helga Olkowski. The Taunton Press., Inc.,

Internet:

- National Pest Control Association: http://www.pestworld.org
- Biocontrol Network: http://bioconet.com

APPENDIX H
First Aid in the Laboratory

Adapted from "National Research Council. 1995. Prudent Practices in the Laboratory: Washington, D.C. (p. 87-88)"

If an individual is injured or contaminated with a hazardous substance, tending to him or her generally takes priority over implementing the spill control measures. It is important to obtain medical attention as soon as possible by calling 404/894-2500.

For spills covering small areas of skin, follow these procedures:

1. Immediately flush with flowing water for no less than 15 minutes.
2. If there is no visible burn, wash with warm water and anti-microbial soap, removing any jewelry to facilitate clearing of any residual materials.
3. Check the Material Safety Data Sheet (MSDS) to see if any delayed effects should be expected.
4. Seek medical attention for even minor chemical burns.
5. Do not use creams, lotions, or salves.

Take the following steps for spills on clothes:

1. Do not attempt to wipe the clothes.
2. Quickly remove all contaminated clothing, shoes, and jewelry while using the safety shower.
3. Seconds count, so do not waste time because of modesty.
4. Take care not to spread the chemical on the skin or, especially, in the eyes.
5. Use caution when removing pullover shirts or sweaters to prevent contamination of the eyes; it may be better to cut the garments off.
6. Immediately flood the affected body area with warm water for at least 15 minutes. Resume if pain returns.
7. Seek medical attention as soon as possible.
8. Discard contaminated clothes or have them laundered separately from other clothing.

For splashes into the eye, take these steps:

1. Immediately flush with tepid potable water from a gently flowing source for at least 15 minutes.
2. Hold the individuals' eyelids away from the eyeball, and instruct him or her to move the eye up and down and sideways to wash thoroughly behind the eyelids.
3. Use an eyewash. If one is not available, place the injured person on his or her back and pour water gently into the eyes for at least 15 minutes.
4. Seek medical attention as soon as possible.

If the victim is unconscious, has trouble breathing, has chest pain/pressure, is bleeding severely, has possible broken bones, has persistent pain/pressure in the abdomen, is vomiting/passing blood, has headache, seizures, or slurred speech seek medical care by calling 404/894-2500. The police will then inform the medical responders as to where you are located.

Appendix I

OSP USE ONLY
Login Date:
MTA Number
Legal:
OTL:
Compliance:

Georgia Institute of Technology
Materials Transfer Initiation Form

Office of Sponsored Programs
505 10th Street, N.W.
Atlanta, GA 30332-0420

Complete form and return to Office of Sponsored Programs, ReACTT, mail code 0420

Georgia Tech Data

Principal Investigator:	Department:	Mail Code:
Phone:	Email:	

Material Transfer Information

For an outgoing MTA use the UBMTA.
For an incoming MTA please attach the proposed agreement.

Is the material ☐ Outgoing or ☐ Incoming to Georgia Tech?

Original Material:

Origin of Material:
☐ Animal ☐ Human ☐ Other

How will the material be used? (Be specific)

Is special handling or storage required?
☐ Yes ☐ No If YES, please explain: _____

1. Are these Material(s) included in the USA Patriot Act or in the Georgia Board of Regents list of select agents?
   ☐ Yes ☐ No
2. Are these Materials human embryonic stem systems
   ☐ Yes ☐ No
3. Please list all funding source(s) (federal and non-federal) along with any OSP Project Number for the research in which the Material will be used.
4. Is the Material(s) requested associated with an invention already disclosed to the Office of Technology Licensing?
   ☐ Yes ☐ No Disclosure No. _____

Material Provider/ Recipient Information

Provide/Recipient Organization: Phone Number: ( )

Name of Contact: Address:

Outgoing MTA

For an outgoing MTA use the UBMTA which is located on the web at http://www.osp.gatech.edu/forms.htm

5. Was this Material(s) (or any part of the Material) created in any lab other than your current facility at Georgia Tech?

   ☐ Yes ☐ No

If you answered YES to the question above, please indicate and list the original owner, their organization, and the Georgia Tech MTA file number below.

6. Are there any provisions associated with this MTA?

   ☐ Yes ☐ No

If YES, explain your provisions.

Call 404/894-6944 for assistance.

Incoming MTA

For an incoming MTA please attach the proposed agreement

5a. Will the Material(s) be used in research that is subject to any licensing, consulting, or other obligations on inventions created in your research?

☐ Yes ☐ No

5b. Will the Material(s) be used in combination with any materials you have received or will receive from any other institution, corporation, or business entity?

☐ Yes ☐ No

5c. Is the Material(s) commercially available?

☐ Yes ☐ No

If you answered YES to either question above, please indicate the organization and the obligations below.

_____

6. Royalty Free License: Some MTA's require the recipient to grant a royalty-free license to the provider. This means neither you nor the University will be entitled to any compensation from any inventions should they arise out of your research using these Material(s).

a) Do you anticipate making any inventions as a result of your research utilizing the provided material(s)?

☐ Yes ☐ No

1. If YES, please describe the inventions which you believe may be developed:

_____

2. If YES, please fill out attached memo and return with this form.

b) If you answered YES to Question 6a, is it acceptable to grant the provider organization a royalty-free license to any such inventions?

☐ Yes ☐ No ☐ N/A

7. Ownership: The language in some MTAs state that the company shall OWN any derivatives (including modified and unmodified) you create while using the Material in your Research. This means neither you nor the University will be entitled to any compensation whatsoever from any derivatives created during this Research.

a) Do you anticipate making any derivatives of the provided Material?

☐ Yes ☐ No

b) Are you willing to allow the organization to own derivatives you create?

☐ Yes ☐ No ☐ N/A

8. Presentations & Publications The MTA may require you to submit to the providing Company or Institution any proposed publication or oral presentation relating to this research _____ days prior to submission or presentation.

Is this publication delay acceptable?

☐ Yes ☐ No ☐ N/A

If NO, how many days preferred? _____ Please note that delays fewer than thirty (30) days are frequently unacceptable to the provider.

Incoming MTA (continued)

Institutional Review Board	Institutional Animal Care & Use Committee
If human subjects are involved, provide IRB protocol number: _____	If animal subjects are involved, provide IACUC protocol number: _____
Biosafety Committee	**Biohazards**
If recombinant DNA is involved, provide biosafety protocol number: _____	If biohazards (chemical, sharps, biological, other) are involved, attach copy of authorization letter from Environmental Health & Safety. _____

Biological, Etiological, and Pathogenic Organisms

If biological, etiological and/or pathogenic organisms are involved, provide BEAPO Committee protocol number:

_____

Disposal of Materials:
(Please indicate whether materials are to be returned to provider. If not, describe how and when the materials will be disposed of).

Certification:

I certify that I have read and understand the Institute's policies and procedures regarding Sponsored Programs; and I will comply with any condition or restriction imposed by the Material Transfer Agreement (MTA).

Signature of Georgia Tech Scientist Requesting Materials — Date

Approvals:

Signature of Department Head — Date

Signature of Associate Vice Provost for Research — Date

Today's Date

Dear Dr. _____:

RE: Royalty-free, non-exclusive license within your Materials Transfer Agreement with Institution

If you have answered Yes to Section 6a., it is necessary to have both you and your Department Chair read this letter and sign below.

At this time, I want to make sure that you understand and agree that subject to the provisions of this MTA the Department/School of _____ and Dr.____ will not be entitled to any royalties from any discoveries and/or inventions made through the use of the materials provided to Dr.____ under this agreement.

If this is acceptable to both you and your Department Chair, please sign in the appropriate spaces provided at the bottom of this letter.

Thank you for your attention and assistance.

Best regards,

Rosibel Ochoa, Ph.D.
Technology Licensing Associate
Georgia Tech Research Corp.
Office of Technology Licensing

APPROVED

_____ _____
Principal Investigator Department Chair

Please print the following items:

Name: Name:

Date: Date: